Citation:

Goodrow EF, Wilson TA, Houde SC, Vishwanathan R, Scollin PA, Handelman G, Nicolosi RJ. Consumption of one egg per day increases serum lutein and zeaxanthin concentrations in older adults without altering serum lipid and lipoprotein cholesterol concentrations. *J Nutr.* 2006 Oct;136(10):2519-24.

PubMed ID: 16988120

Study Design:

Randomized Crossover Trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

- Investigate the effects of consuming 1 egg per day for 5 weeks on serum concentration of lutein, zeaxanthin, lipids, and lipoprotein cholesterol in individuals > 60 years old
- To determine whether egg consumption would result in significant increases in serum LDL-cholesterol concentrations.

Inclusion Criteria:

- > 60 years of age
- Not currently taking lutein and/or zeaxanthin supplements
- Not currently taking cholesterol-lowering medications
- English-speaking

Exclusion Criteria:

- < 60 years old
- Taking lutein or zeaxanthin supplements
- Taking cholesterol-lowering medications
- Persons who did not speak English comfortably

Description of Study Protocol:

Recruitment: Study participants were recruited from 4 nursing homes, 4 senior citizens centers, and from the University of Massachusetts in Lowell faculty and staff. Methods of recruitment were not described.

Design: Randomized crossover trial. This was an 18-week crossover study that consisted of 4 phases:

- Phase I was a baseline period in which participants were instructed to limit their consumption of foods high in lutein and zeaxanthin and to avoid eggs or high-egg content foods.
- Phase II was a 5-week intervention during which subjects consumed either no egg or egg substitute or 1 egg per day in addition to their normal diet.
- Phase III was a 4-week washout period similar to Phase I.
- Phase IV consisted of a 5-week cross-over intervention period in which those subjects who consumed no egg were switched to 1 egg/day in addition to their normal diet and those who consumed 1 egg/day in Phase II were switched to the no egg or egg substitute group.

Participants were interviewed at baseline. Blood pressure, height, and weight were recorded. A Mini-Mental State Examination was administered to verify mental competence. A 7-day diet record was obtained form each subject once during each phase of the study. Dietary intakes for a number of nutrients, including energy, protein, carbohydrate, dietary fiber, total fat, monounsaturated fat, polyunsaturated fat, saturated fat, and cholesterol were assessed. Percent energy intake from protein, fat, carbohydrates, and alcohol were assessed.

During each phase, serum lipids were evaluated based on 12-hour fasting blood samples.

Blinding used (if applicable): There was no blinding during the study or during analysis or lab results or nutrient analysis.

Intervention (if applicable). Consumption of 1 egg/day

Statistical Analysis:

- Differences between the 4 phases were determined by a 1-way ANOVA.
- When differences were observed, a Student-Newman-Keuls test was used.
- A paired *t* test was used to examine the effect of the egg versus no-egg phases on the different variables measured.

Data Collection Summary:

Timing of Measurements:

- The study was conducted over 18 weeks.
- Participants were interviewed at baseline. Blood pressure, height, and weight were recorded. A Mini-Mental State Examination was administered to verify mental competence.
- Phase I was 4 weeks, phase II was 5 weeks, phase III was 4 weeks, and phase IV was 5 weeks.
- During each phase, serum lipids were evaluated based on 12-hour fasting blood samples.

Dependent Variables

- Serum lutein as measured by high-performance liquid chromatography
- Serum zeaxanthin as measured by high-performance liquid chromatography
- Serum total cholesterol as measured using a Cobas Mira Plus Clinical Chemistry Autoanalyzer
- Serum triglyceride as measured using a Cobas Mira Plus Clinical Chemistry Autoanalyzer

- Serum HDL-cholesterol as measured using EZ DDL Cholesterol Reagent
- Serum LDL-cholesterol as calculated using the Friedewald equation

Independent Variables

- Consumption of 1 egg per day
- A 7-day diet record was obtained form each subject once during each phase of the study. Dietary intakes for a number of nutrients, including energy, protein, carbohydrate, dietary fiber, total fat, monounsaturated fat, polyunsaturated fat, saturated fat, and cholesterol were assessed. Percent energy intake from protein, fat, carbohydrates, and alcohol were assessed.

Control Variables

Description of Actual Data Sample:

Initial N: Sixty-five individuals were recruited for the study. Nineteen were excluded due to the onset of illness, death, or nonadherence to protocol. Thirteen were excluded due to taking a lutein and/or zeaxanthin supplement. After eliminating these subjects, the n was 33 subjects (7 men and 26 women).

Attrition (final N): No attrition. All 33 subjects were accounted for.

Age: Subjects ranged in age from 60 to 96 years old. Mean age of men was 77 ± 4 years and women were 81± 2 years.

Ethnicity: All but one subject were Caucasian; that subject that was an Asian or Pacific Islander.

Other relevant demographics: Twenty nine of the subjects had graduated high school or college.

Anthropometrics: Mean weight for men was 78 kg ±4.5 and for women was 70 kg ± 2.7.

Location: Lowell, Massachusetts.

Summary of Results:

Key Findings:

- Serum lutein and zeaxanthin concentrations during the 4-week phase prior to consuming 1 egg/day increased 26 and 38% respectively by the end of the 5-week intervention period (both $P < 0.001$).
- Serum TC, LDL-C, HDL-C, and TG concentrations during the no-egg and egg interventions did not differ.
- Serum lutein and zeaxanthin concentrations during the no-egg and egg interventions were only significantly associated with HDL-C.
- No significant changes in the dietary intake were observed between participants that were free-living versus those that were institutionalized.
- The only macronutrient that increased during the egg intervention versus the non-egg period was dietary cholesterol (451 ± 24 for egg vs 312 ± 50).

Association between serum concentrations of lutein and zeaxanthin before and after egg consumption with serum lipids and lipoprotein cholesterol concentrations

	No egg r	No egg r^2	No egg P-value	Egg r	Egg r^2	Egg P-value
TC	0.200	0.040	NS	0.121	0.015	NS[2]
Lutein	0.025	0.001	NS	0.133	0.018	NS
Zeaxanthin						
LDL-C	0.159	0.025	NS	-0.02	0.0001	NS
Lutein	-0.075	0.006	NS	0.015	0.0001	NS
Zeaxanthin						
HDL-C	0.410	0.168	<0.017	0.453	0.205	0.008
Lutein	0.325	0.106	NS	0.424	0.180	0.014
Zeaxanthin						
TG	-0.233	0.054	NS	-0.133	0.018	NS
Lutein	-0.150	0.023	NS	-0.144	0.021	NS
Zeaxanthin						

r=Pearson's correlation coefficient, r^2= proportion of variance explained uniquely by a particular variable, NS=not significant

Author Conclusion:

These findings indicate that in older adults, 5 weeks of consuming 1 egg/day significantly increases serum lutein and zeaxanthin concentrations without elevating serum lipids and lipoprotein cholesterol concentrations.

Reviewer Comments:

- *The n in this study was very small, most subjects were female and the age range in this study was very broad, from 60 to 96 years old with a mean age of 79.*
- *There was no information provided on blinding of subjects or those who analyzed the data.*
- *Compliance to dietary restrictions/food intake was measured by a 7-day intake record. Information was self-reported and is therefore subject to reporting error.*
- *Supported by the American Egg Board*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	No
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	No
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	N/A
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A

3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	N/A
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	N/A
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	No
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes

6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	Yes
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	Yes
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes

9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	No
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	No